



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,641	06/11/2001	Cato T. Laurencin	DRE-0055	2890

26259 7590 09/21/2005

LICATLA & TYRRELL P.C.  
66 E. MAIN STREET  
MARLTON, NJ 08053

EXAMINER
----------

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/878,641

Applicant(s)

LAURENCIN ET AL.

Examiner

Urmi Chattopadhyay

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on 8/22/05 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09/878,641 is acceptable and a RCE has been established. An action on the RCE follows.

### ***Response to Amendment***

2. The Declaration under 37 CFR 1.132 filed 8/22/05 is insufficient to overcome the rejection of claims 1-11 based upon a specific reference applied under 35 U.S.C. 103(a) as set forth in the last Office action because: the declaration compares the claimed subject matter to the Chervitz (USPN 4,417,699) reference, which is not the closest prior art. The closest prior art is the Wolowacz et al. (WO 95/01810) reference. See MPEP 716.02(e), below.

#### **716.02(e) [R-2] Comparison With Closest Prior Art**

An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). "A comparison of the claimed invention with the disclosure of each cited reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference." In re Merchant, 575 F.2d 865, 868, 197 USPQ 785, 787 (CCPA 1978) (emphasis in original). Where the comparison is not identical with the reference disclosure, deviations therefrom should be explained, In re Finley, 174 F.2d 130, 81 USPQ 383 (CCPA 1949), and if not explained should be noted and evaluated, and if significant, explanation should be required. In re Armstrong, 280 F.2d 132, 126 USPQ 281 (CCPA 1960) (deviations from example were inconsequential).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. (WO 95/01810 A1, as cited in applicant's IDS) in view of Chervitz (USPN 4,917,699 as cited in previous office action).

Wolowacz et al. discloses a replacement construct for tendons or ligaments with all the elements of claims 1 and 2, but is silent to the braided scaffold being a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique. The ligament replacement (page 1, lines 3-5) includes a braided polymeric fiber-based (page 16, lines 32-35), degradable scaffold (page 2, lines 5-11). The scaffold is seeded with cells (page 1, lines 27-30) using a method that implies that the scaffold is porous (page 17, lines 19-21). See page 8, lines 20-21 for the ingrowth of the cells being supported by the scaffold. Chervitz teaches a prosthetic ligament comprising a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique in order for an individual strand of fiber to extend in all directions within the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 2, lines 43-49 and column 3, lines 1-27. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the

Art Unit: 3738

teachings of Chervitz to modify the standard braided scaffold of Wolowacz et al. to a three-dimensional braided scaffold formed using a three-dimensional textile braiding technique in order for the prosthetic ligament to generate strength and elasticity akin to that for natural ligaments. The three-dimensional braiding also provides the optimal orientation for a plurality of fibers to substantially replicate the behavior of natural ligament and the increased fiber redundancy to reduce cracks. See column 1, lines 26-32 and 43-50.

Claim 3, see page 2, lines 1-3 for the cells being fibroblasts, which are mesenchymal in origin.

Claims 6 and 7, see page 1, lines 3-5 and page 5, lines 4-16 for a method of replacing a damaged ligament.

Claim 8, see pages 16-17, steps (a)-(c) of Example 1 for a method of producing a graft material composed of living cells in a degradable matrix comprising harvesting and culturing cells in a culture and seeding the cultured cells onto the scaffold of claim 1 by sucking cell suspension through the scaffold under vacuum.

Claim 9, see page 16, lines 18-20 for the cells being fibroblasts, which are mesenchymal in origin.

5. Claims 4, 5, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolowacz et al. in view of Chervitz as applied to claims 2 and 8 above, and further in view of Vacanti (USPN 5,855,610 as cited in previous office action).

Wolowacz et al., as modified by Chervitz, discloses a replacement construct for tendons or ligaments and a method of producing a graft material with all the elements of claims 2 and 8,

Art Unit: 3738

including the cells being precursor cells to fibroblasts (page 2, lines 1-3), but is silent to the cells generating mesenchymal cells, as required by claims 4 and 10, and of the cells being pluripotent stem cells, as required by claims 5 and 11. Vacanti et al. teaches a replacement construct comprising a degradable, polymeric fiber-based, porous scaffold seeded with cells, wherein the cells are pluripotent stem cells because they are immunologically inert. See column 6, lines 50-53. It would have been obvious to one of ordinary skill in the art to modify the replacement construct of Wolowacz et al. by seeding the scaffold with pluripotent stem cells, which are cells that generate mesenchymal cells, because they are immunologically inert.

### ***Response to Arguments***

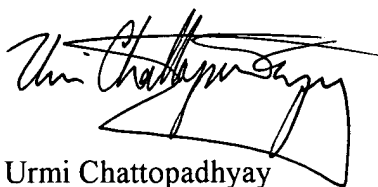
6. Applicant's arguments filed 8/22/05 have been fully considered but they are not persuasive. Applicant states "the Examiner's suggested substitution of the braided polyester yarns used by Chervitz with a degradable polymer such as taught by Wolowacz et al. (WO 95/01810 A1) would have altered the intended purpose and/or principle of operation of the permanent replacement ligament of Chervitz et al." The examiner had never made such suggestion. As set forth in the rejection under 35 U.S.C. 103(a), the only modification made would be to the ligament replacement of Wolowacz et al., and NOT to the construct of Chervitz et al. The modification is making the standard braided scaffold of Wolowacz et al. a three-dimensional braided scaffold using a three-dimensional textile braiding technique, as taught by Chervitz et al. This proposed modification would not render the ligament replacement of Wolowacz et al. unsatisfactory for its intended purpose.

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

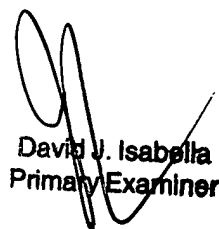
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella  
Primary Examiner